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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,964	01/28/2002	Yasuko Rikihisa	22727/04109	8510

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EXAMINER

SWARTZ, RODNEY P

ART UNIT.

PAPER NUMBER

1645

DATE MAILED: 07/01/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,964

Applicant(s)

RIKIHISA ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 26 and 28-30 is/are allowed.
- 6) ☒ Claim(s) 15-19 and 24 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicants' Response to Restriction, received 19 June 2003, paper#8, is acknowledged. Applicants elect, without traverse, Invention I, claims 15-19, 24-26, and 28-30, drawn to method and kit for diagnosis of *Ehrlichia* infection, classified in class 435, subclass 7.35.

Applicants' Second Preliminary Amendment, received 19 June 2003, paper#9, is acknowledged. Claims 15, 16, 17, 18, 19, 29, and 30 have been amended.

2. Claims 15-20 and 24-30 are pending. Claims 20 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

3. Claims 15-19, 24-26, and 28-30 are under consideration.

Drawings

4. Figures 1 and 3-34 are objected to because M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Appropriate correction is required.

Claim Objections

5. Newly amended claim 15 is objected to because of the following:
- a) line 5, "(I.) an" is not underlined as new to the claim and "a" or "selected from the group consisting of the polypeptide of claim 9, the polypeptide of claim 3, and mixtures thereof:" of the original claim has not been deleted,
 - b) the names of bacteria are not italicized as are other designations in the application,
 - c) line 8, there are two commas following "protein",

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- d) line 12, "proein" should be "protein",
- e) line 17, "proteing" should be "protein"; in addition "proteing" has not been underlined indicating addition to original claim, nor has "polypeptide" been bracketed indicating that the term is to be deleted,
- f) line 20, "polypeptide" in the original claim has not been bracketed indicating that the term is to be deleted; also, "wherein" has been partially underlined; "immunoreative" should be "immunoreactive",

Appropriate correction is required.

6. Newly amended claim 19 is objected to because of the following:

- a) the names of bacteria are not italicized as are other designations in the application,

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is dependent from claim 5 which has been canceled.

10. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 step (b) is unclear because the step contains "ii)", but does not contain reference "I)", and the language of reference "ii)" appears to be repeated twice.

11. Claims 15-19 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:32, does not reasonably provide enablement for variants of the polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims 15 and 19 are drawn to a method of diagnosing an infection with *E. chaffeensis* or *E. canis* comprising providing a "variant" of the P30 protein or a "variant" of a purified outer membrane of *E. canis*.

The instant specification defines "variant" as a protein whose amino acid sequence is similar to P30 but which has ≥ 1 amino acids in the reference sequence deleted, substituted, or inserted with another amino acid. However, the specification does not define the "variant" as

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having the same immunological characteristics as the reference polypeptide. Therefore, utilizing of variants which do not have the same immunological characteristics as the reference polypeptide constitutes merely an invitation to experiment without a reasonable expectation of success.

Claims 16-17 and 24 depend from rejected claim 15.


Conclusion

12. Claims 15-19 and 24 are rejected. Claims 25, 26, and 28-30 appear to be allowable over the prior art due to the unique sequence and fragments of the claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

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June 30, 2003